In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 1, 2021

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DIANA CASTANEDA, *as mother and Natural guardian of minor child,* S.E.C.,	*	PUBLISHED
Petitioner,	*	No. 18-1958V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Influenza (Flu); Guillain-Barré syndrome (GBS); Statute of Limitations; Lookback Provision; Table Injury; Reflexes; Alternative Diagnosis.
Respondent.	*	
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Mallori B. Openchowski, United States Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On December 21, 2018, Diana Castaneda ("petitioner") filed a claim in the National Vaccine Injury Compensation Program.[2] Petition (ECF No. 1). The claim concerns petitioner's minor child S.E.C.'s receipt of an influenza ("flu") vaccination on December 21, 2014, followed by his alleged development of Guillain-Barré syndrome ("GBS") on or shortly before February 1, 2015. Petition at Preamble, ¶ 2. Following a review of all of the evidence submitted and for

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

the reasons detailed below, I hereby **DENY** respondent's motion to dismiss the claim and **GRANT** petitioner's motion for a ruling on entitlement.[3]

I. Relevant Procedural History

Petitioner initiated her claim on December 21, 2018. It was initially assigned to the Chief Special Master's Special Processing Unit ("SPU"). Petitioner filed supporting medical records and her affidavit as Petitioner's Exhibits ("Pet. Exs.") 1-13, 16-19.

On August 5, 2019, respondent filed a motion to dismiss which relied on his concurrent report pursuant to Vaccine Rule 4(c) ("Resp. Report"). ECF Nos. 14-15. Respondent argued that the claim should be dismissed because it was not timely filed. Resp. Report at 7. Respondent acknowledged that the Act contains a lookback provision for the filing of petitions pursuant to revisions to the Table. *Id.* at 8-9, citing 42 U.S.C. § 300aa-16(b). Respondent has revised the Table to create a presumption of compensation for any petition filed on or after March 21, 2017, for the receipt of a flu vaccine followed within 3 – 42 days by the onset of GBS meeting certain qualifications and aids to interpretation ("QAI"). *Id.* at 7-8, citing 42 C.F.R. § 100.3(a); § 100.3(c)(15); *see also* 82 Fed. Reg. 620401, 2017 WL 202456 (Jan. 19, 2017). However, respondent argued that S.E.C. did not have "decreased or absent deep tendon reflexes in weak limbs" required for a Table flu/GBS injury. *Id.* at 7-8, citing 42 C.F.R. § 100.3(c)(15)(ii)(A). Respondent also argued that S.E.C.'s diagnosis was "unclear." *Id.* at 8.

On August 22, 2019, the Chief Special Master deferred ruling on respondent's motion to dismiss and ordered petitioner to file a medical expert's report addressing the issues that had been identified. ECF No. 17.

On January 15, 2020, petitioner filed a supportive report from Ahmet Höke, M.D., Ph.D.[4] Pet. Ex. 14; *see also* Pet. Ex. 15 (curriculum vitae); Pet. Exs. 20-28 (cited medical literature). The Chief Special Master transferred the case out of the SPU and randomly to my docket. ECF Nos. 23-24.

[3] Pursuant to Section 13(a)(1), in order to reach my decision, I have considered the entire record, including all of the medical records, expert testimony, and literature submitted by the parties. This opinion discusses the elements of the record I found most relevant to the outcome.

[4] Dr. Höke is licensed to practice medicine in the state of Maryland and he is board-certified in neurology. Pet. Ex. 15 at 34-35. He obtained a medical degree from Hacetteppe University in Turkey in 1988, followed by a Ph.D. in neuroscience from Case Western Reserve University in Cleveland, Ohio in 1994. *Id.* at 1. He received post-graduate training in internal medicine, neurology, and neuromuscular medicine. *Id.* at 1-2. Since 1999, he has been employed at Johns Hopkins University in Baltimore, Maryland. *Id.* at 1. He is currently a full Professor of Neurology and Neuroscience, Director of the Neuromuscular Division, Director of the Neuromuscular Fellowship, and Co-Director of the Neuromuscular Histopathology Laboratory. *Id.* In addition to his clinical and academic commitments, Dr. Höke "conducts translational laboratory research on pathogenesis of peripheral neuropathies and nerve regeneration." Pet. Ex. 14 at 1. He has published numerous peer-reviewed works and serves as an editor for various journals focusing on neurology. Pet. Ex. 15 at 1-34.

At the March 9, 2020, initial status conference, I commented that Dr. Höke was well-qualified and that he credibly addressed the features of S.E.C.'s injury that were perhaps unusual for GBS. I noted that to establish a Table flu/GBS claim, a petitioner is required to establish the absence of an identified more likely alternative diagnosis, but not required to rule out alternative causes for GBS, at least at the outset when seeking the benefit of the lookback provision. If the case proceeds on the merits, respondent has the opportunity to raise any such alternative causes, such as an intervening viral illness. ECF No. 25. I also questioned whether S.E.C.'s more recent complaints were indeed residual effects of GBS versus unrelated double-jointedness and/or carpal tunnel syndrome. Petitioner duly conveyed a demand, but respondent was not amenable to settlement discussions. ECF Nos. 30, 33.

A second status conference took place on November 30, 2020. I noted Dr. Höke's observation that the records from S.E.C.'s initial hospitalization contained inconsistent notations about his reflexes, even on a given day. However, there were multiple notations of diminished reflexes. I also discussed the objective EMG/NCV and CSF analysis findings, the absence of a more likely alternative diagnosis, and respondent's burden of establishing a more likely alternative cause.[5] I directed petitioner to identify case law on the lookback provision and respondent to file a responsive expert report. ECF No. 36.

On January 4, 2021, petitioner filed a brief identifying past cases that applied the Vaccine Act's lookback provision to on-Table versus off-Table GBS claims. ECF No. 39.

On January 28, 2021, respondent advised that he had retained an expert witness who required additional time to finalize his report in this case. Therefore, respondent requested that his deadline to file the expert report be extended until March 3, 2021, which petitioner did not oppose and I granted. ECF No. 40.

Then, on March 1, 2021, respondent advised that he did not intend to file additional evidence and requested that the Court "resolve the factual question of whether petitioner has satisfied the Vaccine Injury Table for GBS," particularly, the QAI's requirement of "decreased or absent deep tendon reflexes in weak limbs." Respondent's Motion for a Factual Ruling ("Resp. Mot.") at ECF No. 41. The motion did not address petitioner's position. Afterwards, my law clerk emailed both parties' counsel for clarification and a schedule was adopted for briefing.

On April 8, 2021, petitioner filed a motion for a ruling on the record. ECF No. 43. Respondent filed a response on May 10, 2021. ECF No. 44. Petitioner filed a reply on May 26, 2021. ECF No. 45. The matter is now ripe for adjudication.

[5] I also suggested that S.E.C. could undergo testing for antibodies and T cells for *campylobacter jejeuni* and any other suspected alternative explanations for GBS. ECF No. 36. Petitioner declined to pursue this testing after receiving Dr. Höke's opinion that there would be no medical utility for S.E.C. to undergo such testing six years after the initial course.

II. Evidence Submitted

A. Medical Records

The minor at issue, S.E.C., was born in November 2009. His medical history was significant for eczema, a penile abnormality that was surgically repaired in 2010, and one febrile seizure in 2012. Pet. Ex. 2 at 1; Pet. Ex. 6 at 33-70. Also in January 2012, S.E.C. had an orthopedic evaluation for a two-week history of inhibited use of his right hand and possibly left hand. Pet. Ex. 6 at 63. The physical examination was normal and the impression was a possible mild strain which was not presenting any obvious functional problem. *Id.*

S.E.C. received regular primary care at the office of Izak Reischer, M.D., in Forest Hills, Queens, New York. For each medical appointment, Dr. Reicher utilized a pre-printed sheet listing various physical systems including "neuro" in a column, followed by another column headed "normal" which he would generally draw a line through. These columns are presumably intended to reflect the physical exam. Dr. Reischer also handwrote the patient's vitals, findings and abnormalities, history, impression/ diagnosis, and treatment/ plan. *See generally* Pet. Ex. 2.

S.E.C. received the flu vaccination at issue when he was five years old, on December 21, 2014, at Dr. Reischer's office. Pet. Ex. 6 at 52. Dr. Reischer recorded only "afebrile, flu shot" and drew a line through all systems; there is no express reference to reflexes, strength, or other neurological findings. *Id.*

The next medical encounter is twenty-four (24) days post-vaccination, on January 14, 2015, again with Dr. Reischer, who recorded that all systems were normal except for head & neck (recorded as "not stiff") and nose/ oral ("runny nose"). Pet. Ex. 6 at 50. However, S.E.C. had a fever reaching 101 degrees Fahrenheit (measured as 99 degrees Fahrenheit during the encounter), left ear pain, headache, runny nose, cough, neck hurts, "ROS NIC" [meaning unclear] and "tolerating [illegible]." *Id.* Dr. Reischer's impression was a viral syndrome; he counseled S.E.C.'s mother on fever control and said to follow up as needed. *Id.*

At the next encounter twenty-nine (29) days post-vaccination, on January 19, 2015, Dr. Reischer drew a line through the physical exam column, then linked "skin" to his findings of papular rash on his back and chest, dry skin, diarrhea, and continued fever. Pet. Ex. 6 at 50. Dr. Reischer counseled S.E.C.'s mother on dietary considerations for diarrhea. *Id.*

At the next encounter forty (40) days post-vaccination, on January 30, 2015, Dr. Reischer again drew a line through the physical exam column. Pet. Ex. 6 at 48. He referred to the last visit's review of systems. He recorded "not a cold feeling," chills, headache, and cough. *Id.* His impression was a viral syndrome. *Id.*

At S.E.C.'s next medical encounter forty-two (42) days post-vaccination, on February 1, 2015, Dr. Reischer drew a line through the physical exam column except for what appears to be the letter R next to "extremity" accompanied by a small human figure with what appears to be the letter 2 drawn on each side (although the figure is so small that it is impossible to ascertain whether these numbers refer to particular parts of the body). Pet. Ex. 6 at 48. Dr. Reischer

found that S.E.C. was afebrile but had difficulty walking, joint pain, balance problems, increased urination, head pain, fatigue, some unclear finding pertaining to his muscles, and he was falling when walking. *Id.* Dr. Reischer's impression was "cerebellar ataxia[6] versus Guillame-Barre[7] [sic], Transverse Myelitis"[8] for which S.E.C. was referred for emergency medical attention. *Id.*

That same day, February 1, 2015 at approximately 1:50 p.m., the mother brought S.E.C. to the emergency room at Cohen Children's Hospital[9,10] in Hyde Park, New York. Pet. Ex. 7 at 1. A triage nurse recorded the mother's history, but no physical exam findings. *Id.* at 98. Afterwards, an emergency physician, Nafis Khan, M.D., recorded that S.E.C. had "normal reflexes", but that a neurology fellow would evaluate S.E.C. to "r/o [rule out] GB[S], cerebellar disease." *Id.* at 106, 108.

On February 1, 2015, at 6:30 p.m., at Dr. Khan's request, a neurology fellow, "L. Vargas"[11] conducted a pediatric neurology inpatient consult. Pet. Ex. 7 at 70-73. Dr. Vargas recorded that S.E.C. had experienced diarrhea and a fever which subsided. *Id.* at 70. "On Thursday[,] [January 29, 2015,] it was noted [S.E.C.] was weak and he was complaining of generalized pain. Friday[,] [January 30, 2015,] mother noticed his gait was not normal (ataxic)." *Id.* On neurologic exam, S.E.C.'s bilateral upper extremity strength was 4-5 /5 and his lower extremity strength was 4+/5 but he was unable to hop on one foot. *Id.* at 72. Deep tendon

[6] The cerebellum is posterior to the brainstem and is concerned in the coordination of movements. Ataxia is defined as failure of muscular coordination. Acute cerebellar ataxia may be associated with disease, tumor, or trauma, and results in marked hypotonia on the affected side, with asynergy and assumption of a characteristic posture. *Dorland's Medical Dictionary Online*, at https://www.dorlandsonline.com (hereinafter "*Dorland's*").

[7] As further discussed below, Guillain-Barré syndrome ("GBS") is an "acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes." 42 C.F.R. § 100.3(c)(15)(i).

[8] Myelitis is defined as inflammation of the spinal cord. In transverse myelitis, the functional effect of the lesions spands the width of the entire cord at a given level. *Dorland's*.

[9] In reviewing S.E.C.'s course while at Cohen Children's Hospital, I have particularly reviewed the neurologists and other doctors' contemporaneous handwritten records. *See* Pet. Ex. 7 at 20-78.

[10] At the time in question, the hospital was part of North Shore Long Island Jewish health system; it subsequently became part of Northwell Health.

[11] Lines Vargas, M.D., was serving as a fellow in clinical neurophysiology in 2015. Northwell Health – Residency in Child Neurology at Cohen Children's Medical Center, https://professionals.northwell.edu/graduate-medical-education/fellowship-child-neurology-cohen-childrens-medical-center (last accessed May 11, 2021).

reflexes[12] were 2+ bilaterally in the upper extremities and the knees,[13] but only 1+ at both ankles.[14] *Id.* Plantar reflexes were recorded as "↓↓." *Id.* S.E.C. demonstrated ataxia but not dysmetria;[15] sensation was responsive and appropriate for his age. *Id.* Dr. Vargas ordered a lumbar puncture, cerebrospinal fluid analysis, and infectious disease testing. *Id.* at 73.

Also on February 1, 2015, attending neurologist Joseph Maytal, M.D., evaluated S.E.C., and pediatrics resident Alexandra Kilinsky, D.O., entered the findings including from the neurological exam. Pet. Ex. 7 at 113-32. S.E.C. was recorded to have "gait: ataxic and wide based, does not appear to favor a particular side, motor: 4/5 strength UE and LE, no cerebellar signs, sensation grossly intact." *Id.* at 118, 125. With regard to reflexes, the same record provides: "2+ DTRs b/l patella" but does not address the ankles, which were recorded as abnormal earlier that same day. *Id.* at 118, 125.

Dr. Maytal's impression was most likely GBS. Pet. Ex. 7 at 121. A lumbar puncture and CSF analysis was "consistent with albuminocytologic dissociation." *Id.*; *see also id.* at 185-86 (reflecting elevated protein of 56.9 mg/dL and no white blood cells).

Dr. Maytal also noted S.E.C.'s preceding febrile illness with diarrhea and commented that "the most common preceding illness [for GBS] is campylobacter… can also be seen after mycoplasma, CMV." Pet. Ex. 7 at 121. But a rapid respiratory viral panel was negative for numerous pathogens including mycoplasma pneumoniae. *Id.* at 183-84. Testing for cytomegalovirus was ordered, then automatically cancelled after three days when a sample was not received. *Id.* at 186, 273-74. PCR testing for Epstein-Barr virus was negative. *Id.* at 187. A review of the records did not identify any testing for campylobacter jejeuni.

Following Dr. Maytal's evaluation late on February 1, 2015, S.E.C. was admitted and started on a 5-day course of IVIg. Pet. Ex. 7 at 78, 121.

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[12] A deep tendon reflex is defined as "an involuntary contraction of a muscle after brief stretching caused by percussion of its tendon." *Dorland's*. "Deep tendon (muscle stretch) reflex testing evaluates afferent nerves, synaptic connections within the spinal cords, motor nerves, and descending motor pathways. Lower motor neuron lesions (e.g., affecting the anterior horn cell, spinal root, or peripheral nerve) depress reflexes; upper motor neuron lesions (i.e., non-basal ganglia disorders anywhere above the anterior horn cell) increase reflexes." George Newman, M.D., Ph.D., Albert Einstein Medical Center, *Introduction to the Neurologic Examination* (May 2020), within *Merck Manual – Professional Version*, available at https://www.merckmanuals.com/professional/neurologic-disorders/neurologic-examination/introduction-to-the-neurologic-examination (last accessed May 26, 2021).

[13] Patellar reflex (also called knee jerk, quadriceps jerk, knee jerk reflex, and quadriceps reflex) is defined as: "contraction of the quadriceps and extension of the lower limb when the patellar ligament is tapped." *Dorland's*.

[14] Triceps surae reflex (also called Achilles jerk, ankle jerk, triceps surae jerk, and Achilles, Achilles tendon, or ankle reflex) is defined as: "Plantar flexion of the foot caused by a twitchlike contraction of the triceps surae muscle, elicited by a tap of the Achilles tendon preferably while the patient kneels on a bed or chair, the feet hanging free over the edge. *Dorland's*.

[15] Dysmetria involves improper estimation of distance in muscular acts, with disturbance of the power to control the range of muscular movement, often resulting in overreaching. *Dorland's*.

On February 2, 2015, at 3:00 a.m., a pediatric resident recorded that S.E.C. had an ataxic gait, decreased reflexes, and 4/5 muscle strength. Pet. Ex. 7 at 20. Within the same record, the pediatric resident's assessment was likely GBS with elevated protein on lumbar puncture, decreased reflexes, and muscle strength. *Id.* at 21. The first dose of IVIg was given. *Id.*

Later on February 2, 2015, a neurologist, Shefali Karkare, M.D., hand-wrote that S.E.C. had tolerated the first IVIg dose well. Pet. Ex. 7 at 22. Dr. Karkare did not mark a box next to muscle strength in the upper and lower extremities, but recorded that strength was 3/5 in the upper extremities, 5/5 at the ankles, and 4/5 somewhere else (illegible). *Id.* He did not mark a box next to muscle tone in the upper and lower extremities but did write "nl [normal] tone." *Id.* He wrote an "X" in the box next to deep tendon reflexes (upper and lower extremities) but did not record any specific findings. *Id.* Dr. Karkare did not mark the box next to test coordination/cerebellar, but he recorded that S.E.C. was unable to stand on one foot. *Id.* He wrote an "X" in the box next to sensation but did not record any specific findings. *Id.* Dr. Karkare also wrote that S.E.C.'s negative inspiratory force ("NIF" in the record)[16] was currently 29, NIF was "improving," but the medical providers would continue "close monitoring of respi[ratory function]." *Id.* at 23; *see also id.* at 142-43 (discharge summary providing that S.E.C.'s NIF was 30 upon admission and decreased to -20 at which point he was placed on a continuous pulse oximeter for monitoring).

On February 3, 2015 at 6:00 a.m., Dr. Karkare observed that S.E.C. had diminished strength assessed as 3/5 in the neck hand grip, and hip and strength of 4/5 at the ankle. Pet. Ex. 7 at 28. Plantar response was "2+ throughout upper ext[remities], 1+ bil [bilateral] lower [extremities?]." *Id.* Dr. Karkare also wrote: "LE [lower extremity] DTRs [deep tendon reflexes] absent today." *Id.* at 29.

In the first forty-eight hours of the hospitalization, S.E.C. was placed on a pulse oximeter to monitor his breathing. *See* Pet. Ex. 7 at 143. On February 4, 2015, at about 1:00 a.m., S.E.C. developed increased difficulty breathing, hypertension, increased weakness, pain in his legs and hands, and his fingers "kept getting stuck" in the bent position. *Id.* Rapid response was called. *Id.* On exam, S.E.C. was initially unable to straighten the ring finger on his right hand. *Id.* The responding physician, Rachel Zhang, M.D., was "unable to assess reflexes." *Id.* at 30, 143. S.E.C. was subsequently transferred to the pediatric intensive care unit ("PICU"). *Id.* at 143. Subsequent PICU progress notes do not address his reflexes. *Id.* at 34-37.

On February 4, 2015 at 12:00 p.m., Dr. Karkare observed that S.E.C. had 3/5 strength and 2+ deep tendon reflexes in the upper extremities, and 4/5 strength and 1+ deep tendon reflexes in the lower extremities. Pet. Ex. 7 at 32-33. Dr. Karkare also wrote that S.E.C.'s respiratory difficulty, tachycardia, hypertension, flushing, and sweating were "likely autonomic involvement

[16] Negative inspiratory force ("NIF") is another term for maximum inspiratory pressure, which is defined as a measure of the strength of the respiratory muscles, obtained by having the patient inhale as strongly as possible with the mouth against a mouthpiece; the maximum value is near the residual volume. *Dorland's*; *see also* Medscape, *How Often Should Negative Inspiratory Force Be Monitored in Guillain-Barré syndrome (GBS)?*, available at https://www.medscape.com/answers/315632-14209/how-often-should-negative-inspiratory-force-nif-be-monitored-in-guillain-barre-syndrome-gbs (last accessed June 1, 2021) (providing that normal NIF is "usually greater than 60 cm water").

of GBS." *Id.* at 33. An attending PICU physician recorded that S.E.C.'s GBS was in the context of a preceding febrile diarrheal illness. *Id.* at 34.

That evening in the PICU, while receiving his fourth IVIg dose, S.E.C. developed a pruritic urticaria rash on his chest, for which he was given Benadryl. Pet. Ex. 7 at 143.

On February 5, 2015, a critical care physician, Sabrina Rahman, M.D. observed that S.E.C.'s "b/l patellar reflexes [were] intact" but did not address the ankles, upon transferring him back to the floor for the fifth and final dose of IVIg which was tolerated with Benadryl. Pet. Ex. 7 at 39, 143.

On February 5, 2015, Dr. Karkare observed that S.E.C. was improved and able to talk more, he no longer had autonomic instability or hypertension, his neck and grip strength, his gait was still wobbly, and he would likely need inpatient rehabilitation. However, Dr. Karkare did not address reflexes. Pet. Ex. 7 at 40-41; *see also id.* at 42-43 (February 6, 2015, note by Dr. Karkare with similar findings).

On February 7, 2015, a pediatric neurology resident, Nagma Dalvi, M.D., recorded that deep tendon reflexes were present at the patella and absent at the Achilles heel; she also recorded "↓ DTRs." Pet. Ex. 7 at 46-47. Attending neurologist Zipora Fefer, M.D., recorded similar deep tendon reflexes of "2+ patella, 1+ ankle" and she added "1+ biceps." *Id.* at 47. These notes are in contrast with records from the same time period by pediatric residents who found that S.E.C. had "reflexes 2+ b/l." *Id.* at 44, 47.

On February 8, 2015, the neurology resident Dr. Dalvi and neurology attending Dr. Fefer recorded that S.E.C. continued to have weakness and an unsteady wide-based gait, his exam was "unchanged" and deep tendon reflexes specifically at the ankles were "brisk," but they did not record the knees or the upper extremities. The plan included consulting with nephrology about S.E.C.'s continued hypertension and consulting anesthesiology about performing MRIs of the spine.[17] Pet. Ex. 7 at 52-53.[18] The next neurology progress note does not address reflexes, *see id.* at 54-57, but a pediatric resident recorded that patellar reflexes were 2+, *id.* at 60.

On February 11, 2015, the pediatric neurologist Dr. Maytal marked, in his handwritten record, that on neurological exam, S.E.C. had normal findings in several areas including muscle strength, muscle tone, deep tendon reflexes, tandem gait and Romberg, and sensation. Pet. Ex. 7 at 62. He did not write any specific findings. *Id.*

[17] The MRIs were unremarkable. Pet. Ex. 7 at 666-68.

[18] Drs. Dalvi and Fefer also considered EMG/NCV studies. Those were not conducted during the hospitalization and were first conducted upon S.E.C.'s follow-up with the other neurologist Dr. Karkare in June 2015, *see* Pet. Ex. 5 at 15-21.

The discharge records provide that on neurological exam, S.E.C. was: "Alert and oriented. 5/5 upper and lower extremity strength. 2+ patellar reflexes. Sensation intact." Pet. Ex. 7 at 143. S.E.C. was stable for transfer to Blythedale Children's Hospital ("Blythedale") for inpatient rehabilitation. *Id.* at 11-12.

While at Blythedale from February 11 – March 13, 2015, S.E.C. underwent physical therapy that was focused on improving his strength and stability. *See generally* Pet. Ex. 6. There is one single notation pertaining to reflexes. It states: "Reflexes: Development reflexes appropriately integrated." *Id.* at 3. However, he had "limited higher gross motor skills of dynamic balancing, skipping, jumping, and running." Pet. Ex. 6 at 13. He also had hyperpronated feet, for which he was fitted for ankle braces. *Id.* at 13, 15.

On March 1, 2015, a pediatric neuromuscular physiatrist, Dr. Capoor, conducted an initial consult. Pet. Ex. 2 at 1-2. She recorded S.E.C.'s history of acute and progressive weakness, fatigue, and bilateral leg and back pain followed by hospitalization at Cohen Children's and Blythedale. *Id.* at 1. He also had fine motor dysfunction in his hands and was wearing pull-ups because of incontinence. *Id.* Dr. Capoor's history does not address reflexes. *Id.* He recorded on exam that S.E.C.'s strength remained diminished with bilateral deltoids at 4-; bilateral triceps/ wrist extensors/ grip at 4; hand intrinsics of 4 on the right and 3+ on the left; and hip abductors at 3+. *Id.* at 2. Tandem gait was worse on the left and there was very mild dysmetria with left finger to nose. *Id.* at 2-3. Deep tendon reflexes were +2 at the elbow, knee, and ankle. *Id.* at 3. Dr. Capoor assessed that S.E.C. had GBS with proximal greater than distal weakness, ataxia, and fatigue, which symptoms were improving over time. *Id.* at 4. S.E.C. would continue with physical and occupational therapies three times per week, be careful to avoid fatigue and overheating, and begin aqua therapy to improve core strengthening and coordination. *Id.*[19] Also in March 25, the primary care provider Dr. Reischer and the nephrologist Dr. Singer concurred that S.E.C. was gradually improving. Pet. Ex. 6 at 3; Pet. Ex. 11 at 1-2.

On March 19, 2015, S.E.C. was brought by his grandfather to the first outpatient follow-up neurology evaluation with Dr. Karkare. Pet. Ex. 4 at 18-19. Dr. Karkare recorded that the grandfather was a "poor historian" and therefore telephoned the mother to obtain a better history. *Id.* While Dr. Karkare had been one of the attending neurologists during the initial hospitalization approximately six weeks earlier, there is no indication that he reviewed the hospital records upon creating this new record and S.E.C.'s history of present illness. Dr. Karkare recorded a history of GBS with some typical features including "elevated protein in the CSF without pleocytosis," "autonomic symptoms like hypertension," and "treat[ment] with full dose of IVIg" followed by improvement. *Id.* at 18. However, the history also included

[19] Dr. Capoor also planned a follow-up evaluation with S.E.C. in three months. Pet. Ex. 2 at 4. However, this did not occur on the intended schedule. "A few weeks after the initial visit," the mother called and Dr. Capoor agreed to see S.E.C. informally that same day. Dr. Capoor later recalled that this second encounter was not a "formal medical visit" and she did not make any formal records or bill for services. *Id.* at 5, 7. Dr. Capoor's medical record from the first encounter does reflect that she and S.E.C.'s mother both graduated in 1993 from "TMLA," *see id.* at 2, which from a brief internet search may be a reference to the Mary Louis Academy, a private Catholic high school for young women located in Queens, NY, where Dr. Capoor's practice is also located. *See* The Mary Louis Academy, *About TMLA*, https://www.tmla.org/about-tmla/ (last accessed May 21, 2021).

"atypical features includ[ing] preserved and at one stage brisk DTRs [deep tendon reflexes]." *Id.* At this follow-up encounter, Dr. Karkare observed that S.E.C.'s strength, gait, and reflexes were normal; S.E.C. had "made a full recovery but needs continued therapies as outpatient." *Id.* at 19. Dr. Karkare maintained an assessment of GBS. *Id.* With regard to the specific GBS variant present, Dr. Karkare recorded that the absence of both anti-GQ1B antibodies and ophthalmoplegia[20] made "Miller-Fisher syndrome less likely." *Id.* He ordered EMG/NCV studies "to characterize if this was a predominantly axonal variant of GBS." *Id.*

On March 25, 2015, S.E.C. began outpatient physical and occupational therapies for residual weakness in his trunk and legs (right more than left), decreased ambulation and transfers, gait abnormality, and decreased balance. Pet. Ex. 10 at 59-62. The initial treatment plan was for two sessions per week for four weeks but was extended into July 2015. *See generally* Pet. Ex. 10.

The first EMG/NCV studies, performed on June 5, 2015, yielded findings "consistent with a mixed primarily axonal polyneuropathy with some features of secondary demyelination with chronic and ongoing denervation," as well as a superimposed carpal tunnel syndrome in the right upper extremity. Pet. Ex. 5 at 27-31.[21]

Nearly a year later, on May 9, 2016, Dr. Karkare had a second outpatient appointment with S.E.C. accompanied by his mother. Pet. Ex. 4 at 13-17. Dr. Karkare repeated verbatim the history of present illness from his March 19, 2015, record. *Id.* at 13. Dr. Karkare then noted the initial EMG/NCV findings and that S.E.C. was stable with slow writing speed and less athleticism than his peers. *Id.* On physical exam, he had normal confrontational strength and normal reflexes, but low tone and could not hop on one foot "as well expected for age." *Id.* at 14. Dr. Karkare recommended physical therapy and services at school and planned a repeat EMG/NCV studies for the continued "suboptimal" motor endurance. *Id.*

The repeat EMG/NCV studies, performed on June 23, 2016, yielded findings indicative of a "severe sensorimotor axonal neuropathy of the right median nerve as well as mild motor axonal neuropathy of the right common peroneal nerve." Pet. Ex. 5 at 5-6. These findings were "mostly stable with slightly improved motor conduction of the right common peroneal and ulnar nerves and worsening of the right median motor and sensory nerves without evidence of carpal tunnel syndrome." *Id.* at 6.

On August 10, 2016, Dr. Karkare observed that S.E.C. again had hyperextensible joints, low normal tone, and difficulty hopping on one foot. Pet. Ex. 4 at 22. S.E.C. also demonstrated a Gowers maneuver.[22] *Id.* Dr. Karkare planned to "watch him closely for any fluctuations in motor strength" and recommended occupational therapy. *Id.*

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[20] Opthalmoplegia is defined as paralysis of the eye muscles. *Dorland's*.

[21] Petitioner's expert Dr. Höke, at Pet. Ex. 14 at 3, cites to a less legible scan of the EMG/NCV studies which is found at Pet. Ex. 5 at 10-13.

[22] The Gowers maneuver describes where a patient rolls from the supine to the prone position, kneels, and pushes up to a standing position with hands against shins, knees, and thighs. *Dorland's*.

At a May 15, 2017, follow-up appointment, Dr. Karkare recorded again that S.E.C.'s history began with acute symptoms and hospital admission for GBS in February 2015, after which he had residual fatigue and difficulty with fine motor activities. Pet. Ex. 4 at 2.[23] Dr. Karkare noted that S.E.C. also had hyperextensible joints, for which he was referred to rheumatology to rule out Ehlers-Danlos syndrome.[24] Pet. Ex. 4 at 2-7.

On August 28, 2017, Beth Gottlieb, M.D., the director of pediatric rheumatology at Cohen Children's, evaluated S.E.C. for his hypermobility. Pet. Ex. 12 at 2-6. Dr. Gottlieb observed that on exam, S.E.C.'s "thumb bends back to reach the forearm, fingers bend back parallel to the forearm, hyperextension of the elbows and knees, pronated flat feet." *Id.* at 5. Dr. Gottlieb recorded that these findings were "typical" for benign hypermobility, also known as ligamentous laxity or "being double-jointed." *Id.* at 6. This condition was one of the most common causes of joint pain in school-aged children, which typically occurs after a lot of activity and can resolve even without treatment within minutes. *Id.* Dr. Gottlieb recommended NSAIDS and Tylenol for pain as well as supportive shoes. *Id.*

On February 8, 2018, Dr. Karkare recorded that S.E.C. was stable with problems including GBS, axonal polyneuropathy, and joint hyperextensibility of multiple sites. Pet. Ex. 16 at 1. The physical exam was abnormal for low tone, deep tendon reflexes of 1+, and inability to hop on either foot. *Id.* at 2. Dr. Karkare ordered a third set of EMG/NCV studies. *Id.* at 3. He referred S.E.C. and his mother to an infectious disease specialist to address concerns about further vaccinations. *Id.*

S.E.C. and his mother consulted with a Dr. Rubin, who approved further vaccinations. Pet. Ex. 17 at 45. On March 1, 2018, the primary care provider Dr. Reischer administered a Tdap vaccination into the muscle of S.E.C.'s (non-dominant) left arm. *Id.* at 46. On March 15, 2018, Dr. Reischer administered an IPV vaccination using the same method and site. *Id.* at 44.

On March 28, 2018, a nurse practitioner who worked with Dr. Karkare saw S.E.C. for the complaint of new decreased mobility in his right fingers since March 23, 2018. Pet. Ex. 16 at 4-6. The nurse practitioner recorded incorrectly that S.E.C. had received the IPV vaccination just three days prior, on the 20th. *Id.* at 4, 5. She recorded that it was "unclear if right hand weakness is related to recent immunization." *Id.* at 6. She reiterated the need for repeat EMG/NCV studies. *Id.*

[23] Farther down in this May 15, 2017, record, in the assessment, Dr. Karkare wrote that S.E.C. had "a chronic ill-defined history of fine motor delays who developed acute episode…" Pet. Ex. 4 at 3. Taken out of context, this notation could suggest that S.E.C.'s motor delays began *before* the December 2014 flu vaccination and the early 2015 onset of alleged GBS. However, the limited medical records, which are mostly from his primary care provider rather than neurologists or other relevant specialists, do not support such a finding.

[24] Ehler's-Danlos syndrome (which Dr. Karkare abbreviates to "EDS") encompasses a group of inherited disorders of connective tissue. Prominent manifestations include hyperextensible skin and joints, easy bruisability, and friability of tissues with bleeding and poor wound healing, with additional symptoms specific for individual types. *Dorland's*.

Dr. Reischer administered a subcutaneous MMR vaccination on May 24, 2018, and an intramuscular varicella vaccination on June 14, 2018, both times, again, in S.E.C.'s nondominant left arm. Pet. Ex. 17 at 37, 39.

On August 20, 2018, repeat EMG/NCV studies (ordered by Dr. Karkare to assess for ongoing poor motor control) were consistent with a stable, slightly improved sensory motor axonal neuropathy and superimposed carpal tunnel syndrome. Pet. Ex. 5 at 15-16.

On November 26, 2018, Kate Nellans, M.D., an orthopedic surgeon at Cohen Children's, recorded that in early 2015, S.E.C. had developed GBS with initial flaccidity in the right arm, followed by the onset of right hand and finger pain and inability to tuck the right middle and ring fingers into a tight fist. Pet. Ex. 9 at 5. Dr. Nellans recorded that these problems "appea[r] to be related to the flu vaccine he received in 2015." *Id.*[25] Dr. Nellans assessed that S.E.C. had an adhesion at the A1 pulley between the flexor digitorum superficialis ("FDS") and flexor digitorum profundus ("FDP") tendons, for which she scheduled surgical release. *Id.* at 6. Subsequent records reflect that S.E.C. underwent the surgical release on December 7, 2018, after which he received occupational therapy for ongoing right hand and finger weakness and stiffness. Pet. Ex. 18 at 1.

On January 14, 2019, Dr. Karkare and his nurse practitioner had another follow-up encounter with S.E.C. Pet. Ex. 16 at 7-9. They repeated the incorrect history that S.E.C. received the IPV vaccination just three days prior to the onset of right finger weakness in March 2018. *Id.* at 7-8. The physical exam was remarkable for hyperextensible joints, mild decreased strength in the right hand, deep tendon reflexes of 1+, and inability to hop on either foot. *Id.* at 9. The continued assessment was joint hyperextensibility of multiple sites as well as axonal polyneuropathy. Dr. Karkare and the nurse practitioner recommended consulting a neuromuscular specialist for evaluation and genetic testing to further investigate the cause, which the mother chose to defer because the symptoms were not debilitating. *Id.*

B. Petitioner's Expert Dr. Höke

Dr. Höke opined that the medical records clearly support that after the December 21, 2014 flu vaccination,[26] S.E.C. developed GBS, summarized as "a clearly progressive syndrome characterized by weakness in all limbs, ataxia, autonomic dysfunction, and albuminocytologic dissociation." Pet. Ex. 14 at 4. Dr. Höke also noted that based on the presumptive diagnosis of GBS, S.E.C. was started on IVIg on February 2, 2015. *Id.* at 2.

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[25] As noted above, S.E.C. actually received the flu vaccination on December 21, 2014. Pet. Ex. 6 at 52.

[26] Dr. Höke relied on Dr. Karkare's records from over a year after the flu vaccination, for the proposition that "At the time of his influenza vaccination on 12-21-2105, [S.E.C.] had the "chronic ill-defined history of fine motor delays." Pet. Ex. 14 at 1, citing Pet. Ex. 4. As noted above, the contemporaneous medical records do not support that S.E.C. had any neurological symptoms prior to the vaccination. Additionally, to the extent that Dr. Höke interpreted the records to accept that S.E.C. had some degree of prior neurological issues, he did not deem those to be specific or significant enough to detract from his assessment of GBS beginning after the December 21, 2015, flu vaccination.

Dr. Höke noted that respondent "questioned the GBS diagnosis almost exclusively on normal deep tendon reflexes as documented by some, but not all, of [S.E.C.'s] providers." Pet. Ex. 14 at 4. In assessing this issue, Dr. Höke focused on the records from the initial hospitalization in February 2015 and he observed that those records are inconsistent, even those from a particular provider or a particular day. *Id.*, citing Pet. Ex. 7 at 20, 22-23, 29, 47.

Dr. Höke also opined that loss of reflexes is "not universal in GBS," Pet. Ex. 14 at 5, although he did not refer directly to the Vaccine Injury Table and the QAI which require that sign. He opined that S.E.C.'s onset of symptoms attributable to GBS was within the Table time frame and that alternative diagnoses such as transverse myelitis were eliminated. *Id.* at 5. Finally, Dr. Höke offered a concise opinion that flu vaccination can and did cause GBS in this case, relying in part on the mechanism of molecular mimicry. *Id.* at 5-7.

III. Legal Standard[27]

The Vaccine Act was established to compensate for vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Human Servs.,* 35 Fed. Cl. 1, 7 (1996) (quoting H.R. No. 908 at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6287, 6344).

A petitioner bears the burden of establishing his or her entitlement to compensation from the Vaccine Program. The burden of proof is by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1). There are two separate means of establishing entitlement to compensation. First, the petitioner may establish the receipt of a vaccine listed on the Vaccine Injury Table, followed by the onset within a corresponding timeframe of a corresponding injury, as defined on the Table and the accompanying Qualifications and Aids to Interpretation (the "QAI"). This is termed a "Table injury," for which entitlement to compensation is presumed and the burden shifts to respondent to establish a more likely alternative cause. 42 U.S.C. §§ 300aa-13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, he or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The Vaccine Act includes a statute of limitations. Any petition concerning a vaccination occurring after October 1, 1988, must be filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." 42 U.S.C. § 300aa-16(a)(2). The statute of limitations begins to run on the "date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical profession at large," with no consideration of when the petitioner or any other

[27] Decisions of special masters and the U.S. Court of Federal Claims (some of which are referenced in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

individual first drew a potential causal connection between the vaccine and the injury alleged. *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (*en banc*). The present claim concerns a flu vaccination administered on December 21, 2014, and the alleged onset of GBS on or shortly before February 1, 2015. Petition at Preamble, ¶ 2. The petition filed on December 21, 2018, was nearly a year outside of the limitations period.

Theere are certain exceptions to the statute of limitations. Equitable tolling is available for example, if the petitioner is a victim of fraud or duress. *Cloer*, 654 F.3d at 1344. More recently, the Federal Circuit recognized that equitable tolling may be available upon a sufficient showing of mental incapacity. *K.G. v. Sec'y of Health & Human Servs.*, 951 F.3d 1374 (Fed. Cir. 2020). In the present case, petitioner does not make any argument and I do not see any basis for considering equitable tolling.

The Vaccine Act also includes a lookback provision, as follows:

> (b) Effect of Revised Table. If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, *eligible to seek compensation under the Program*, or *to significantly increase the likelihood of obtaining compensation*, such person may, notwithstanding section 300aa-11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if –
>
> 1) The vaccine-related death occurred more than 8 years before the date of the revision of the table, or
>
> 2) The vaccine-related injury occurred more than 8 years before the date of the revision of the table.

42 U.S.C. § 300aa-16(b) (emphasis added).

The lookback provision contains two key clauses, emphasized above. There is little dispute that the first clause addresses the addition of entirely new vaccinations to the Table. *See Gorski v. Sec'y of Health & Human Servs.*, No. 97-156V, 1997 WL 739497, at *4 (Fed. Cl. Spec. Mstr. Nov. 13, 1997). This has occurred before and could conceivably occur in the future with the addition of, for example, vaccines against COVID-19 or polysaccharide-type vaccines against streptococcus pneumoniae. This first clause also addresses the expansion of eligibility to new categories of individuals. *See Struck v. Sec'y of Health & Human Servs.*, No. 17-1326V, 2018 WL 1514598, at *5 (Fed. Cl. Spec. Mstr. Feb. 9, 2018) (discussing that the 21st Century Cures Act clarified that separate injury claims can be filed by or on behalf of first, a woman receiving a covered vaccine during pregnancy, and second, her *in utero* child). However, this first clause cannot apply to S.E.C.'s case because seasonal flu vaccines were listed on the Table and his mother was eligible to file this claim on his behalf throughout the limitations period.

There is also consensus, with regard to the second clause, that the addition of a new Table injury "significantly increase[s] the likelihood of obtaining compensation" for injuries meeting the definition and accompanying QAI for that new injury. *Gorski*, 1997 WL 739497, at *4.

However, it is not settled whether the addition of a new Table injury also significantly increases the likelihood of obtaining compensation for an injury that does not fit completely within the Table's specific requirements. Here, respondent cited *Gorski*, in which former Special Master Hastings concluded that it was "irrelevant" whether a Table injury and the injury in question were similar because in the latter scenario, the petitioner still needed to establish causation-in-fact. Resp. Report at 9-10, citing *Gorski*, 1997 WL 739497, at *5. In that case, former Special Master Hastings did not accept that the "by adding 'chronic arthritis' as a Table injury, the Secretary of Health and Human Services was somehow *adding credence* to the *general theory* that the rubella vaccine can cause chronic arthritis, thereby adding weight to the 'actual causation' argument of *any* person who developed chronic arthritis after a rubella vaccination." *Id.* Former Special Master Hastings wrote: "In every case, the evidence as to actual causation must be evaluated on its own scientific merit." *Id.*

Respondent has also cited *Randolph*, in which Chief Special Master Corcoran granted the respondent's motion to dismiss a facially untimely claim and not apply the lookback provision, where the petitioner received a seasonal flu vaccination and then developed GBS, but with onset well outside of the 3 – 42 day period specified on the Table. Resp. Response at 11, citing *Randolph v. Sec'y of Health & Human Servs.*, No. 18-1231V, 2020 WL 542735 (Fed. Cl. Spec. Mstr. Jan. 2, 2020). Chief Special Master Corcoran found persuasive the reasoning in *Gorski*. *Castaneda*, 2020 WL 542735, at *10-12. He recognized the Vaccine Program's "policy goals of petitioner leniency and generosity," but noted that flu/GBS claims were "litigated, often successfully, before the March 2017 amendment, and thus the amendment did not create out of whole cloth a new kind of cognizable injury." *Id.* at *11, citing *Corder v. Sec'y of Health & Human Servs.*, No. 08-228V, 2011 WL 2469736, at *1 (Fed. Cl. Spec. Mstr. May 31, 2011). He also emphasized that a petitioner with a facially untimely claim for an injury with at least some similarity to a newly listed Table injury receives some benefit from the lookback provision. *Id.* The petitioner receives the opportunity to argue that the claim fits within the Table's requirements, which can involve offering additional evidence about any factual disputes, such as the true onset of the condition in *Randolph*. *Id.*

In contrast, petitioner contended that any time that the Secretary recognizes that "the scientific and medical evidence is sufficient to warrant a change to the Vaccine Injury Table, petitioners significantly increase their likelihood of obtaining compensation." Pet. Mot. at 2. Petitioner (presumably based on her counsel's past experience in the Vaccine Program) disagreed that the existence of earlier off-Table flu/GBS claims is dispositive because in those claims, "the Secretary consistently contested that the flu vaccine caused GBS, both in litigated cases and in cases respondent ultimately agreed to settle on the basis of litigative risk." Pet. Mot. at 2. Petitioner also argued that a new Table injury can support a finding that the vaccine at issue can actually cause the same or a similar injury. *Id.*, citing *Ling v. Sec'y of Health & Human Servs.*, No. 18-858V, 2019 WL 2606774, at *6 (Fed. Cl. Spec. Mstr. May 21, 2019) (in which Special Master Moran contemplated that a petitioner "may be able to simply cite to the revisions on the Table" to establish that the flu vaccine can cause GBS), review denied, 145 Fed. Cl. 778

(2019). Petitioner also cited to *Simpson*, in which then-Chief Special Master Dorsey reasoned that Congress wrote the first clause, on expanded eligibility, "narrowly [and] precisely" and that "Congress could have used similarly definite language to restrict the second group of claimants, those whose likelihood of obtaining compensation was 'significantly increased,' but declined to do so." Therefore, then Chief-Special Master Dorsey concluded that the lookback provision permitted new Table injuries as well as similar causation-in-fact claims. *Simpson v. Sec'y of Health & Human Servs.*, No. 17-944V, 2019 WL 11815360, at *7 (Fed. Cl. Spec. Mstr. Aug. 7, 2019).[28]

While both parties' arguments are well-taken, it is not necessary to reach whether the lookback provision can save an off-Table injury, because there is still the potential for a Table injury in this case. Pet. Mot. at 3. Petitioner has cited *Hill*, in which Special Master Horner reviewed that the petitioner's claim was for a Table flu/GBS injury, but certain treating physicians had diagnosed CIDP. He reasoned: "Given the conflicting opinions of the treating physicians and drawing all inferences in petitioner's favor, it remains possible that petitioner can provide additional expert medical opinion establishing that she more likely than not suffered a course of GBS consistent with a Table injury rather than CIDP, rendering moot respondent's legal argument favoring dismissal." *Hill v. Sec'y of Health & Human Servs.*, No. 19-384V, 2020 WL 7231990, at *3 (Fed. Cl. Spec. Mstr. Nov. 13, 2020).

Similar to *Hill*, in this case, both parties have asked for a factual determination as to whether S.E.C.'s injury is consistent with a Table GBS injury, specifically the requirement of "decreased or absent deep tendon reflexes." Pet. Mot. at 3, 5; Resp. Response at 7; *see also Gorski*, 1997 WL 739497, *4 ("whether petitioner's injury fits within that new Table injury category… involves essentially a factual determination").

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa-11(c)(2). Medical records "warrant consideration as trustworthy evidence," particularly in describing contemporaneous events. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

While the diagnoses, conclusions, and medical judgments contained in the medical records must be considered, "[a]ny such diagnosis, conclusion, judgment, test result, report, summary shall not be binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). "In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court." *Id.* Competing opinions, diagnoses, and findings should also be weighed against one another. *See, e.g.*, *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (holding that the special master did not abuse his discretion while weighing treating physicians'

[28] The Federal Circuit has actually held that respondent's recognition of a link between a specific vaccine and a specific injury, through its addition to the Vaccine Injury Table, supports petitioner's burden under *Althen* prong one. *Doe 21 v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds*, *Paterek v. Sec'y of Health & Human Servs.*, 527 Fed. Appx. 875 (Fed. Cir. 2013).

differing opinions as to the petitioner's diagnosis), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012);

The Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, slip op., 2021 WL 2006226, at *4 (Fed. Cir. May 20, 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.* In *Kirby*, the Federal Circuit emphasized that the medical records in question were "silent" about the existence or nonexistence of symptoms that would render the petitioner's injury sufficiently severe to receive compensation under the Vaccine Act. *Id.* *4 (citing *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 538 (2011) (itself citing *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991) (holding that "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance"); *see also La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 2013 (Fed. Cl. 2013) (providing possible explanations for inaccuracies in medical records), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

Where medical records are clear, consistent, and complete, they should be afforded substantial weight. *See Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply; "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Id.* at *19. Medical records may also be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). A petitioner may also offer a medical expert opinion in support of his or her claim. 42 U.S.C. § 300aa-13(b)(1). Ultimately, the special master must consider all of the evidence in making his or her determinations, including disputed facts.

IV. Application

The Vaccine Injury Table recognizes a presumption of causation for petitions filed on or after March 21, 2017, concerning seasonal influenza vaccine followed by the onset within 3 – 42 days of GBS as specified in the accompanying QAI. 42 C.F.R. § 100.3(a); *see also* 82 Fed. Reg. 620401, 2017 WL 202456 (Jan. 19, 2017).

GBS is an "acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes." 42 C.F.R. § 100.3(c)(15)(i). "The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy ("AIDP"), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy ("AMAN") is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and

sensory neuropathy ("AMSAN"), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots." 42 C.F.R. § 100.3(c)(15)(ii). A petitioner alleging a Table injury of AIDP, AMAN, or AMSAN must establish certain key requirements, which are set forth in headings A – E below.

A. Onset within 3 – 42 days of vaccination of bilateral flaccid limb weakness and decreased or absent deep tendon reflexes[29] in weak limbs. 42 C.F.R. §§ 100.3(a), 100.3(c)(15)(ii)(A).

As an initial matter, the contemporaneous medical records do not contain any evidence that S.E.C. had such symptoms before the December 21, 2014 flu vaccination, within three days afterwards, or at the primary care encounters on January 14, 2015 and January 19, 2015. The January 30, 2015 primary care record contains certain illegible handwritten notations. However, the medical records support that S.E.C. developed the onset of joint pain, balance problems, fatigue, muscle problems, and falling while walking (ataxia) within thirty-eight (38) and forty-two (42) days post-vaccination, on February 1, 2015, when his mother brought him back to the primary care provider. Pet. Ex. 6 at 48; *see also* Pet. Ex. 7 at 20 (February 2, 2015, hospital record noting a four-day history of pain and difficulty walking).

Respondent raised concern primarily about the medical records suggesting that S.E.C. had some features that would be "atypical" for GBS, particularly the inconsistent findings pertaining to his deep tendon reflexes. Respondent cites first to the primary care provider's February 1, 2015, record which includes a small hand-drawn stick figure with what appears to be the number two on each side. *Id.* Respondent may be referring to this figure to support that S.E.C. had normal reflexes on the primary care provider's examination. *See* Resp. Response at 3. If the primary care provider's drawing is indeed referring to reflexes, a finding of 2+ would be normal. This may establish S.E.C.'s baseline towards the outset of his neurological condition. However, the figure is also so small and lacking in detail that it is unclear whether reflexes were measured in the upper and/or lower extremities. Additionally, the primary care provider drew an arrow from the stick figure to the note "falling while walking," which suggests that he was assessing S.E.C.'s balance or strength.

Importantly, S.E.C. was also documented to have diminished reflexes in his weak limbs beginning on February 1, 2015, following his admission to Cohen Children's Hospital. A neurology fellow observed 1+ reflexes in both ankles was well as a decreased Babinski reflex. Pet. Ex. 6 at 72. These findings continued over the coming days. On February 2, 2015, S.E.C. developed worsening weakness and then was observed to have decreased reflexes. *Id.* at 20. On February 3, 2015, the neurologist Dr. Karkare recorded that S.E.C. had "1+ bil [bilateral] lower extremities?] and that "LE [lower extremity] DTRs [deep tendon reflexes] absent today." *Id.* at 29. Then on February 4, 2015, S.E.C. developed autonomic hypertension which prevented an

[29] A deep tendon reflex is defined as an "involuntary contraction of a muscle after brief stretching caused by percussion of its tendon; tendon reflexes include the biceps reflex, triceps reflex, quadriceps reflex, and others." *Dorland's*.

assessment of reflexes on at least one occasion. *Id.* at 30, 143. However, several subsequent records note diminished reflexes until at least February 7, 2015. *Id.* at 32, 46-47.

Respondent correctly observed that throughout the same time period, there are medical records which state that S.E.C.'s reflexes were in fact preserved or even "brisk." Several of these records were made by non-neurologists. *See, e.g.*, Pet. Ex. 7 at 106, 108, 118, 125, 39, 143 (ordered chronologically). Some of these medical records do not describe all reflexes at issue – most often omitting reflexes at the ankles. *Id.* at 118, 125, 22-23, 32-33, 39, 143, 52-53, 62, 143 (ordered chronologically). It is also possible that the start of IVIg treatment on February 1, 2015, confounded the reflex findings. *See* 42 C.F.R. § 100.3(c)(i) (providing that "[t]reatment-related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset"). But again, these are multiple competing records indicating diminished or absent reflexes during this same hospital course.

Respondent also emphasized that beginning in late March 2015, upon seeing S.E.C. as an outpatient, the neurologist Dr. Karkare wrote that S.E.C.'s course was "atypical" for GBS based on the existence of "preserved and at one stage brisk" deep tendon reflexes. Pet. Ex. 4 at 18. However, this note does not incorporate Dr. Karkare's own contemporaneous record that he observed S.E.C.'s "absent" reflexes during the acute course. *See* Pet. Ex. 7 at 28. In late March 2015, Dr. Karkare was not reviewing the hospital records, but relying on his own memory and that of S.E.C.'s grandfather (who is described as a "poor historian") and mother (contacted by telephone during the appointment). It is more likely than not that by late March 2015, Dr. Karkare was focused on evaluating S.E.C.'s degree of recovery and what ongoing treatment was needed.

Petitioner's expert neurologist Dr. Höke also reviewed the medical records and opined that "normal deep tendon reflexes were documented by some, but not all, of [S.E.C.'s] physicians" and that there were inconsistent records even from a particular day or a particular provider. Pet. Ex. 14 at 4-5. Dr. Höke observed and I conclude that S.E.C. had at least sporadic diminished reflexes in addition to the other well-documented symptoms including weakness, ataxia, and significant respiratory issues, which were consistently diagnosed as GBS and supported by EMG/NCV studies. Dr. Höke's analysis of the medical records helps to support the conclusion pertaining to S.E.C.'s reflexes being diminished, even though he does not cite the specific QAI language.[30]

I find that a preponderance of the evidence supports that S.E.C. developed bilateral flaccid limb weakness as well as diminished reflexes between 3 – 42 days after the flu vaccination. Thereafter, following a course of IVIg, he showed gradual improvement including most likely in his reflexes, but continued to have various residual symptoms following discharge from Cohen Children's Hospital and from Blythedale.

[30] Dr. Höke goes on to opine that the loss of reflexes is not universal in GBS. Pet. Ex. 14 at 5. This may be true but it is not relevant to whether S.E.C. suffered a Table GBS injury, which requires diminished or absent reflexes.

B. An interval between onset and nadir of weakness between 12 hours and 28 days. 42 C.F.R. § 100.3(c)(15)(ii)(C).

While the parties did not argue this point, to summarize, after S.E.C.'s onset of GBS symptoms in late January 2015 and no later than February 1, 2015, he experienced progressive weakness, pain, and autonomic dysfunction prompting admission to the PICU on February 4, 2015. He was moved out of the PICU the following day and was stable for transfer to inpatient rehabilitation on February 11, 2015. This reflects an appropriate interval between onset and nadir of weakness.

C. Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse) and a monophasic illness pattern. 42 C.F.R. §§ 100.3(c)(15)(ii)(D), 100.3(c)(15)(ii)(B).

The medical records reflect that upon transfer to inpatient rehabilitation, S.E.C. displayed improvement with regard to his strength, stability, and reflexes. He had continued deficits in motor skills. He was consistently described as having a past diagnosis of GBS which was improving, which was separate and distinct from the additional diagnoses of benign hypermobility syndrome and carpal tunnel syndrome.

D. The absence of an identified more likely alternative diagnosis. 42 C.F.R. §§ 100.3(c)(15)(ii)(E), 100.3(c)(15)(v), 100.3(c)(15)(vi).

Respondent contended that S.E.C.'s diagnosis is "unclear" and that the "post-vaccination assessment included a variety of conditions." Resp. Report at 8. But on review, the records do not support an alternative diagnosis for S.E.C.'s condition. Respondent first averred that the primary care provider Dr. Reischer "diagnosed cerebellar ataxia." Resp. Report at 2 (citing Pet. Ex. 6 at 4). However, the medical record states "Cerebellar ataxia vs. Guillame-Barre [sic], transverse myelitis." This record does not support that the primary care provider landed on one most likely diagnosis, but instead, that he was considering three competing conditions in the differential which warranted further evaluation by other providers particularly with expertise in neurology. The primary care provider promptly referred S.E.C. to Cohen Children's Hospital for that more specialized care. The neurologists who evaluated S.E.C. did not support a diagnosis of cerebellar ataxia or transverse myelitis, in fact, they consistently recorded a diagnosis of GBS. *See generally* Pet. Exs. 4, 7.

Respondent also cited the neurologist Dr. Karkare's outpatient records. Resp. Report at 8(citing Pet. Ex. 4 at 2-3, 7-9, 18). Dr. Karkare did write that S.E.C. had "atypical GBS" based on the characterization that S.E.C.'s reflexes were preserved during the initial course, for which I do not find substantial support, as discussed above. When Dr. Karkare referenced Miller-Fisher syndrome, he actually said that it was less likely in light of the absence of both anti-GQ1B antibodies and ophthalmoplegia. Dr. Karkare's reference to "axonal polyneuropathy" is consistent with the remaining GBS variants listed on the Table.

After S.E.C.'s acute course of neurologic and autonomic dysfunction, he was also diagnosed with joint hyperextensibility, which is one of the most common causes of joint pain in school-aged children according to the treating physician Dr. Nellans, the director of pediatric rheumatology at Cohen Children's Hospital. Pet. Ex. 12 at 6. However, Dr. Nellans and the other treaters continued to recognize S.E.C.'s past history of GBS. There is also no evidence that joint hyperextensibility would explain S.E.C.'s acute weakness, autonomic dysfunction, and respiratory insufficiency, much less the objective evidence on cerebrospinal fluid analysis and the electrodiagnostic studies.

Furthermore, the medical records do not reflect any of the diagnoses that would foreclose a Table GBS injury, such as chronic immune demyelinating polyneuropathy ("CIDP").

In the paragraph discussing more likely alternative diagnoses for S.E.C.'s condition, respondent goes on to aver that S.E.C. had a viral syndrome before his hospitalization. Resp. Report at 8. This is not a more likely diagnosis, but an alternative explanation for GBS which will be reviewed below.

E. Additional evidence of GBS, 42 C.F.R. § 100.3(c)(15)(iv)

During S.E.C.'s hospitalization, CSF analysis revealed elevated protein with no white blood cells. Pet. Ex. 7 at 121, 185-86. In addition, on three occasions between 2015 and 2018, S.E.C. underwent EMG/NCV studies which were consistent with GBS. Pet. Ex. 5 at 27-31, 5-6, 15-16 (ordered chronologically).

F. Conclusion on Table GBS Injury and Lookback Provision

For the foregoing reasons, petitioner has established that S.E.C. suffered a Table flu/GBS injury. The new presumption of compensation for precisely this injury significantly increased the likelihood of prevailing with this claim. Therefore, this petition, filed within two years of the Table revision, is timely.

G. Alternative Cause

Compensation may not be awarded if a preponderance of the evidence supports that S.E.C.'s GBS was "due to factors unrelated" to the flu vaccination. 42 U.S.C. § 300aa-13(a)(1)(B). However, such an unrelated factor cannot be "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. § 300aa-13(a)(2)(A). The evidence must support that the unrelated factor is the "more likely or principal cause of injury alleged," which was "principally responsible" for the injury. *Knudsen v. Sec'y of Health & Human Servs.,* 35 F.3d 543, 551 (Fed. Cir. 1994). If the vaccination and the proposed alternative cause are "seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded." *Id.* The government can only rebut petitioner's *prima facie* case by establishing that the proposed alternative cause "was in fact the sole cause (thus excluding the vaccine as a substantial factor)." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1349 (Fed. Cir. 2008); *see also Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344 (Fed. Cir. 1999).

Here, respondent averred that "[T]here is clear record evidence that S.E.C. had a viral syndrome with diarrhea in the two weeks preceding his hospitalization, a known prodrome[31] for GBS." Resp. Rep't at 8 and Resp. Response at n. 8 (citing Pet. Ex. 7 at 34, 121). However, respondent has not proposed a specific pathogen, a theory of how that pathogen can cause GBS, or why that would necessarily be the sole cause of S.E.C.'s GBS, without any implication of the flu vaccine. The medical records reflect that the treating physicians noted the preceding viral illness, however, a rapid respiratory viral panel was negative for numerous pathogens including mycoplasma pneumoniae. Pet. Ex. 7 at 183-84. Testing for cytomegalovirus was ordered, then cancelled. *Id.* at 186, 273-74. PCR testing for Epstein-Barr virus was negative. *Id.* at 187. Testing for campylobacter jejeuni apparently did not occur. Petitioner's expert Dr. Höke reviewed the issue and opined that there is no utility to having S.E.C. tested for campylobacter jejeuni now, more than six years after the onset of his GBS. Pet. Status Report (ECF No. 38). Based on the record as it stands, respondent has not established by a preponderance of the evidence that S.E.C.'s GBS was "due to factors unrelated to the administration of the vaccine."

V. CONCLUSION

As elaborated above, petitioner has established preponderant evidence that she, on behalf of S.E.C., is entitled to compensation for a Table GBS injury. A separate damages order will issue.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master

[31] A prodrome is defined as a "premonitory symptom or precursor; a symptom indicating the onset of a disease." *Dorland's*; *see, also, e.g., Agarwal v. Sec'y of Health & Human Servs.*, No. 16-191V, 2020 WL 5651683, at *12 (Fed. Cl. Spec. Mstr. Aug. 31, 2020) (discussing that in another neurological condition, limbic encephalitis, the prodrome is typically (but not always) marked by neuropsychiatric symptoms such as memory impairment, personality change, behavioral abnormalities, and hallucinations, which occur before the more dramatic onset of seizures). However, a prodrome does not represent an alternative cause.